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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,795	10/20/2000	Frederic Triebel	03715.0069	4063

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EXAMINER
YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
1642	12

DATE MAILED: 02/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/673,795	TRIEBEL ET AL.	
	Examiner	Art Unit	
	Christopher H Yaen	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *7-11,13-15,19-21,29-36,39 and 40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *7-11,13-15,19-21,29-36,39 and 40* is/are rejected.

7)☒ Claim(s) *7-11,13-15,19-21,29-36,39 and 40* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☒ The proposed drawing correction filed on *1/20/02* is: a)☒ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group III in Paper No. 11 is acknowledged. Claim 29 is drawn to non-elected claim and will not be examined on the merits. Claims 7-11,13-15,19-21,29-31,32-36, and 39-40 will be examined on the merits.

Drawings

2. The corrected or substitute drawings were received on 1/20/01. These drawings are approved and while be revised with the corrections upon notification of allowance.

Priority

3. Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this action.

Claim Objections

4. Claims 7-11, 13-15, 19-21, 30-31, 33-36 and 39-40 are objected to because of the following informalities:

The claims define the scope of an invention and must particularly point out and distinctly claim the invention, and must be a single sentence starting "I (We) claim:" or "What is claimed is:." Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 7,11, 13, and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regards to claim 1 and 7, the current claim language is drawn to a non-elected claim, therefore rendering the claim indefinite and unclear. Appropriate correction is required. ✓

In regards to claim 1 and 11, in the recitation of the phrase *"one element"*, it is unclear as to what the applicant intends to claim as the *"one element"* in which the peptide compound is to contain, aside from naturally occurring amino acids. Clarification is required. NO

In regards to claim 1 and 13, in the recitation of the phrase *"peptide fragment"*, it is ambiguous as to the fragment the applicant intends to claim. Currently, as interpreted by the examiner, the phrase reads on any peptide fragment and not a peptide fragment of hsp70. Appropriate correction or clarification is required. NO

In regards to claim 1 and 14, in the recitation of the phrase *"factors which activate immune defenses"*, the phrase is indefinite and unclear. There are many factors, elements or genes which can elicit an immune response. Selection and clarification as to which "*factor*" applicant intends to claim is needed. OK

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 33 and 40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant application invites the skilled artisan to experiment. The factors, which must be considered in determining undue experimentation, are set forth in *In re Wands* 8 USPQ2d 1400. The factors include: 1) quantity of experimentation, 2) the amount of guidance presented, 3) the presence or absence of working examples, 4) the nature of the invention, 5) the state of the prior art, 6) the predictability of the art, 7) breadth of the claims, and 8) the level of skill in the art.

In regards to factor 1, the instant claimed method invites the skilled artisan to participate in undue experimentation to determine the preparative steps needed to prepare the final medicinal product comprising a peptide compound comprising a sequence of at least 8 consecutive amino acids of a natural hsp70 sequence, how much to and how to administer the said medicinal product to a patient in need thereof, and how to provide preventative treatment of cancer. Applicant presents data on *in vitro* tests of CD8 induction in the Elispot assay, but does not transfer this data to an *in vivo* model of treatment. There is no evidence as to how the peptide is to react in an *in vivo* model, or the type of immune response that is elicited upon reactivity to the mutated peptide of hsp70. The experimental quantity required and evaluation of requisite

parameters essential to determine whether mutated hsp70 peptides can treat cancer would require undue experimentation.

In regards to factor 2, the guidance provided in the instant disclosure is insufficient to provide an adequate determination as to whether a mutated peptide of hsp70 can treat cancer. The instant disclosure appears to provide guidance as to how one might: identify mutations within an antigen to be recognized by CTLs, wherein the said antigen is a mutated peptide of hsp70; the production of monoclonal antibodies to mutated hsp70 peptides; peptide synthesis, recognition, and binding; and CD8 induction with mutated peptide *in vitro*. However, the instant disclosure fails to provide guidance as to the *in vivo* preparation, administration, quantity of peptide needed to administer, and effectiveness of peptide in treating cancers of the types disclosed in the instant application. The scope of the broadly claimed methods should find support in the instant disclosure, however, in the absence of the essential steps, it is difficult for skilled artisans to envision how to use the peptide of the instant invention for the treatment of cancer.

In regards to factor 3, the working examples of the instant disclosure are limited to the identification, preparation, and the *in vitro* usage. The ability, to use the hsp70 mutated peptide for the treatment of cancer, is not seen to be adequately supported by the disclosure of the instant specification. The ability of a peptide to treat cancer upon single administration or repeated administration to generate a breakdown of tolerance, requires further guidance or a more adequately represented disclosure to support the same.

In regards to factors 4, 5, 6, it is noted that there is a great deal of unpredictability in the treatment of cancer with peptide fragments. The instant specification fails to provide a specific methodological procedure for which the instant method can or is intended to be used for treating cancer of the types disclosed in the instant application. The art at the time the invention was made fails to establish with regard to the efficacy of peptides in general as an effective means of treating cancer by the generation of an immune response. For example, it is unknown whether the peptide is able to withstand proteolytic degradation, or is able to maintain enough stability to adequately elicit an immune response. The unpredictability associated with the treatment of cancer using peptide fragments would lead an artisan skilled in the art into undue experimentation, to make and use the invention as claimed in the instant application. One of skill in the art, would have to : determine the conditions necessary to manufacture the peptide in such a way as to prevent its clearance from the system, establish an appropriate administration protocol of the peptide, and determine the clinical dosages required to maintain an efficacious effect for the treatment of cancer. All of the criteria set forth above, not being inclusive, is associated with a great deal of unpredictability and experimentation.

In regards to factors 7 and 8, the specification discloses the process of identification, production, and testing *in vitro* of the mutated hsp70 peptide. Such is not seen as sufficient to support the breadth of the claims 33 and 40 of the instant application, where the scope of the claims encompasses *in vivo* efficacy of the instant claimed peptide in treating cancer. It is noted that Law requires that the disclosure of an

application shall inform those of skill in the art how to use applicant's alleged discovery, not how to find out how to use it for themselves, see *In re Gardner et al.* 166 USPQ 138 (CCPA 1970).

Conclusion

9. No claims allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

GEETHA P. BANSAL
PRIMARY EXAMINER

Christopher Yaen
Art Unit 1642
February 20, 2002